Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/674,268	**Applicant(s)** FANTUZZI, MICHAEL	
	Examiner Rosanne Kosson	**Art Unit** 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *14,15,18-20,22,23,32-34,36-43 and 45-51*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 9/22/08
13. ☐ Other: _____.

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657

Continuation of 11. does NOT place the application in condition for allowance because: No claim amendments were filed, only arguments. Applicant's arguments filed on September 22, 2008 have been considered, but they are largely a repeat of previous arguments and are not persuasive for reasons that have been discussed in the previous Office actions. Regarding Applicant's Declaration under 37 CFR §1.131, this Declaration has not been and cannot be rejected; only claims can be rejected. All of Applicant's documents have been considered. But, as previously discussed, the evidence submitted with the Declaration does not show reduction to practice of the subject matter of the instant claims before the priority date of Erwin. Applicant's documents show that he was given the assignment of producing a solution of co Q10 (coenzyme Q10) in d-limonene on March 13, 2003 and that on March 14-19, 2003, Applicant prepared several such solutions. Applicant's position in his responses of July 12, 2007, August 31, 2006, April 28, 2006 and December 20, 2005 is that preparing a soft gel containing a solution of co Q10 in d-limonene is not an obvious modification of making that solution. Thus, in view of the prosecution history, Applicant cannot now assert that the solution is the same thing as the soft gel containing the solution. Further, if making the soft gel preparation is not an obvious modification, the intent to make the soft gel preparation is not reduction to practice. Presumably, technical difficulties are involved in going from the solution to the soft gel preparation. Moreover, it is not clear or explicit in the e-mail of March 13, 2003 what was to be done with the d-limonene solution with respect to the final formulation of the products in which it was to be used. As for the sentence on the notebook page stating that adding pure limonene to a soft gel capsule is not really practical although Soft Gel, Inc. does make such a product, this sentence appears to disclose that a different compound was dissolved in limonene and that then that solution was encapsulated in soft gels as a commercial product. On this date, March 14, Applicant was working out limonene-oil formulations for co Q10. The product was not yet finished.

Regarding Erwin, Applicant asserts that the application is not enabled because Erwin uses a temperature of 42 ºC, while Applicant uses room temperature to prepare the limonene solution of co Q10. But, the instant claims are not product-by-process claims, the different temperatures do not make different products, and there is no evidence that heating at 42 ºC destroys the co Q10, particularly as the instant claims encompass both oxidized and reduced forms. Example 1 on p. 3 of Erwin's provisional application appears to be straightforward for one of skill in the art, such as a chemist or pharmacist. The disclosure does not appear to be hypothetical or prophetic. As for the amount of co Q10 in the d-limonene solution, most of the instant claims do not recite any percentages. Of the claims that do recite percentages, only claims 32 and 42 recite a range for which the lower limit is above 25%. But the term "about" is not defined in the specification, and it cannot be determined what the difference is between 25% and "about 30%." That is, the range of "about 30%" is not specified and may include 25%.

Regarding Weis et al., this reference does disclose a soft gel preparation containing a suspension of 100 mg of co Q10 in 400 mg of soybean oil. But, this is a rather concentrated preparation, 20% by weight of co Q10, which may have exceeded the solubility limit for soybean oil. Weis et al. disclose, however, that the suspension has better bioavailability than the solid dosage form or the emulsions (p. s276). Nevertheless, Weis et al. are not the most relevant prior art, as the claims are drawn to a soft gel comprising a solution of co Q10 in limonene. As previously discussed, Folkers et al. disclose an aqueous emulsion of co Q10 in soybean oil, a soft gel containing co Q10 dissolved in soybean oil and that co Q10 is soluble in various vegetable oils, such as soybean oil (see col. 4, lines 33-46, and col. 6, lines 16-29).

Regarding Soft Gel (the EP reference), as discussed in all of the previous Office actions, Soft Gel discloses a soft gel containing a solution of co Q10 in rice bran oil and vitamin E. Applicant has, at times, taken the position that the content of the soft gel is a suspension, not a solution. But, Soft Gel was never used in an anticipation rejection, and the obviousness rejection is that it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the rice bran oil of Soft Gel with limonene, because Erwin and Garti et al. disclose that co Q10 is soluble in d-limonene.

Davidson et al. have also been discussed in all of the previous Office actions. To reiterate, the claims do not require that the co Q10 be dissolved in the fish oil. The claims recite simply that the composition further comprises the carrier fish oil. But, fish oil was a known nutraceutical at the time of the invention (for reducing atherogenic blood lipids). Also, because co Q10 is a lipophilic compound that is soluble in plant oils, one of ordinary skill in the art at the time of the invention would have expected co Q10 to be soluble in an animal oil.

Regarding an In re: Kerkhoven rejection, there is no In re: Kerkhoven rejection in this case. This type of rejection was made in a copending case, Application No. 10/953328. But, the instant claims are broader with respect to the co Q10 solution and recite a solution of co Q10 in limonene. Certain dependent claims recite that the composition further comprises a carrier that may be soybean oil, but these claims do not recite that the co Q10 is soluble in the carrier. Earlier versions of the copending claims recited a solution of co Q10 in a mixture of limonene and a carrier.

The instant rejection is not a hindsight rejection, as it is based on the prior art, and the reason to combine the references comes from the prior art. As for a long-felt need in the art and a solution containing more than 5% co Q10, as noted by Applicant, co Q10 has been formulated in many different ways to improve its bioavailability (delivery to cells). Thus, many scientists have addressed this problem. The specification, however, does not disclose comparative results for the bioavailability of co Q10 for the claimed product vs. other commercial products or other products disclosed in the literature. Only claims 32, 33, 42 and 43 recite a composition in which the concentration of co Q10 is above 5%, and Erwin discloses 25%. Thus, in view of the teachings of the prior art, the claimed invention is still considered to be an obvious modification of the prior art. .